



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,636	10/19/2001	Sidney T. Smith	FLM-5169	8615
7590	05/09/2005		EXAMINER	
MARK J. BUONAIUTO, ESQ. BAXTER INTERNATIONAL INC. LAW DEPARTMENT ONE BAXTER PARKWAY, DF2-2E DEERFIELD, IL 60015			BISSETT, MELANIE D	
			ART UNIT	PAPER NUMBER
			1711	
DATE MAILED: 05/09/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/044,636	SMITH ET AL.
	Examiner	Art Unit
	Melanie D. Bissett	1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 January 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 3-7,9-18,20,22,23,25,26,28,39-45,61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 3-7,9-18,20,22,23,25,26,28,39-45,61 and 62 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

Art Unit: 1711

1. The rejections based on 35 USC 112 have been withdrawn. However, a new matter rejection has been added, and prior art rejections have been altered to reflect the amended claims.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3-7, 9-18, 20, 22-23, 25-26, 28, 39-45, and 61-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Independent claims 18 and 39 have been amended to contain the recitation of a "DSC melting point lower than about 100 °C". The applicant relies upon an example of Affinity PL 1880 for the support of this limitation. The Affinity material has a DSC melting point of 86 °C. It is the examiner's position that the recitation of this material in the specification does not support the entire range of lower than about 100 °C. It is the examiner's position that the example does not support all materials having a melting point of 86 °C, either, since all materials are encompassed by the claim and one specific

example is given. Thus, the example only provides support for the use of the specific layer structure shown and nothing broader.

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 4-7, 9-18, 20, 22-23, 25-26, 28, 39-45, and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al. as evidenced by DuPont.
7. From a prior Office action:

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Smith teaches a multiple layer structure having solution contact and outer exterior layers, where the outer layers are chosen from polyamides, polyesters, and polyolefins (abstract). The modulus of the overall film is less than 50,000 psi (col. 3 lines 18-28). Polyamide materials include ring-opening products nylon 6, nylon 10, or nylon 12, while condensation products nylon 66, nylon 6,10, and dimer fatty acid polyamides are also included (col. 4 lines 1-14). Single-site catalyzed polyolefins are used, where ethylene-butene copolymers are preferred (col. 4 lines 57-67). Affinity and Exact materials are used, and the copolymers should have densities of 0.880-0.910 g/cc (col. 5 lines 1-3). Tie layers include blends of modified and unmodified polyolefins, where maleic anhydride is a preferred modifying agent (col. 5 lines 4-47). The thicknesses of the layers read on the applicant's claimed ranges (col. 5 line 66-col. 6 line 10).

Regarding slip agents, the reference does not require the use of such slip agents; thus, it is the examiner's position that the reference teaches structures essentially free of slip agents. The layers are coextruded and formed into medical containers (col. 6 lines 38-60).

Regarding the burst pressure of the films, it is noted that the prior art films are made of the same materials and thicknesses as employed by the applicant. Thus, it is the examiner's position that the structures would inherently possess the applicant's claimed burst pressure values.

Regarding the "attached directly" language, the claims are interpreted in the broadest sense; the outer layer of Smith is attached directly to the inner layer through tie and barrier layers.

8. Regarding the new limitation of a DSC melting point, Smith discusses many tie layer materials, including Bynel, Plexar, and other modified and unmodified polyolefins (col. 5 lines 4-54). The reference exemplifies the use of Bynel 4206, which DuPont discloses as having a DSC melting point of 102 °C. It is the examiner's position that this melting point is within experimental error of 100 °C and also within the claimed range of "about 100 °C".

9. Claims 4-7, 9-10, 14-18, 20, 22-23, 25-26, 28, 39-41, and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramesh et al. '392 as evidenced by MatWeb.

10. From a prior Office action:

Ramesh discloses multi-layered films comprising a polyolefin outer layer and an outer layer selected from polyester, polyamide, and polyurethane (abstract). The polyolefin layer comprises a single-site catalyzed homogeneous ethylene/α-olefin polymer having a preferred melting point below 100 °C and a preferred carbon content of 4-8 carbons in the α-olefin (col. 11-col. 12 line 3). The polyolefin also preferably has a density of less than 0.898 g/cc to create a layer of up to 4-mil thickness (col. 15 lines 28-58; col. 16 lines 22-23). Materials for the other outer include the applicant's claimed nylon materials at a thickness of up to 4 mils (col. 19 lines 22-28, 49-50). Tie layers are included at a thickness of 0.13 or 0.16 mils (col. 20 lines 16-20; example 1). The overall films have modulus values as low as 40,000 psi (col. 20 lines 42-50).

Regarding slip agents, the reference does not require the use of such slip agents; thus, it is the examiner's position that the reference teaches structures essentially free of slip agents. The layers are coextruded and formed into packaging containers (col. 1 lines 7-11; examples).

Regarding the burst pressure of the films, it is noted that the prior art films are made of the same materials and thicknesses as employed by the applicant. Thus, it is the examiner's position that the structures would inherently possess the applicant's claimed burst pressure values.

Regarding the "attached directly" language, the claims are interpreted in the broadest sense; the outer layers of Ramesh are attached directly to each other through tie and intermediate layers.

11. Regarding the new limitation of a DSC melting point, Ramesh discloses many tie layer materials (col. 17 lines 9-26; examples). Film No. 1 employs Bynel 2174 tie

layers, where MatWeb discloses that the Bynel material has a DSC melting point of 85 °C.

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims 11-13 and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramesh et al. in view of Adur et al.

14. From a prior Office action:

Ramesh applies as above, teaching the use of tie layers but failing to specify a blend of a modified polyethylene copolymer with a polyolefin polymer. Adur teaches adhesive blends of grafted polyethylene homopolymers or copolymers, LDPE or LLDPE, and a poly(α -olefin), where the blends have improved adhesive strength with both polyolefins and polar substrates (col. 1 lines 36-56; col. 2 lines 4-10). The adhesives can be applied to substrates and co-extruded to form a number of articles (col. 1 lines 57-68). Examples of specific composites are listed, including polyolefin/adhesive/nylon, polyolefin/adhesive/EVOH, and polyolefin/adhesive/polyester (col. 4 lines 15-27). Maleic anhydride is noted as a preferred modifying monomer (col. 2 lines 49-65; examples 40-41, at least). Therefore, it is the examiner's position that it would have been *prima facie* obvious to use the adhesive blend of Adur's teaching in the composite of Ramesh's invention to improve the adhesive strength between the polyolefin and polar substrate.

15. Claims 3 and 62 are rejected under 35 U.S.C. 103(a) as being obvious over Smith et al. in view of Mueller.

16. From a prior Office action:

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the

Art Unit: 1711

claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Smith applies as above, teaching specific polyamides and also teaching copolymers for use as outer layers but failing to note the use of the applicant's claimed polyester ethers. Mueller teaches multilayer films for flexible container purposes, where Ecdel materials are taught as equivalent to nylon 66, nylon 6,10, and nylon 12 as materials providing improved heat resistance and abuse resistance (col. 9 lines 37-53). Ecdel materials are noted by the applicant as PCCE polymers. It is the examiner's position that it would have been *prima facie* obvious to use PCCE polymers as outer layers in Smith's invention to provide multilayer films having equally improved heat resistance and abrasion resistance.

17. Claims 3 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramesh et al. '392 in view of Mueller.

18. From a prior Office action:

Ramesh applies as above, teaching specific polyamides and also teaching polyesters for use as outer layers but failing to note the use of the applicant's claimed polyester ethers. Mueller teaches multilayer films for flexible container purposes, where Ecdel materials are taught as equivalent to nylon 66, nylon 6,10, and nylon 12 as materials providing improved heat resistance and abuse resistance (col. 9 lines 37-53). Ecdel materials are noted by the applicant as PCCE polymers. It is the examiner's position that it would have been *prima facie* obvious to use PCCE polymers as outer layers in Ramesh's invention to provide multilayer films having equally improved heat resistance and abrasion resistance.

Response to Arguments

19. The applicants argue that the references teach away from the claimed invention because they teach additional layers between the exterior layers. As previously stated,

the claims are interpreted in their broadest sense to allow for intermediate layers. The exterior layers of the references are directly attached through intermediate layers, including tie layers. Again, since the specification gives no guidance to limit this term, it is the examiner's position that "attached directly" encompasses the presence of intermediate layers. It is the examiner's position that the "attached directly" cannot be interpreted to allow for tie layers but to exclude any other layers as this would be contradiction.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie D. Bissett whose telephone number is (571) 272-1068. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melanie D. Bissett
Patent Examiner
Art Unit 1711

mdb